

SUBCHAPTER B—OIG AUTHORITIES

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

Subpart A—General Provisions

Sec.

- 1001.1 Scope and purpose.
- 1001.2 Definitions.

Subpart B—Mandatory Exclusions

- 1001.101 Basis for liability.
- 1001.102 Length of exclusion.

Subpart C—Permissive Exclusions

- 1001.201 Conviction relating to program or health care fraud.
- 1001.301 Conviction relating to obstruction of an investigation.
- 1001.401 Conviction relating to controlled substances.
- 1001.501 License revocation or suspension.
- 1001.601 Exclusion or suspension under a Federal or State health care program.
- 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.
- 1001.801 Failure of HMOs and CMPs to furnish medically necessary items and services.
- 1001.901 False or improper claims.
- 1001.951 Fraud and kickbacks and other prohibited activities.
- 1001.952 Exceptions.
- 1001.953 OIG report on compliance with investment interest safe harbor.
- 1001.1001 Exclusion of entities owned or controlled by a sanctioned person.
- 1001.1101 Failure to disclose certain information.
- 1001.1201 Failure to provide payment information.
- 1001.1301 Failure to grant immediate access.
- 1001.1401 Violations of PPS corrective action.
- 1001.1501 Default of health education loan or scholarship obligations.
- 1001.1601 Violations of the limitations on physician charges.
- 1001.1701 Billing for services of assistant at surgery during cataract operations.

Subpart D—Waivers and Effect of Exclusion

- 1001.1801 Waivers of exclusions.
- 1001.1901 Scope and effect of exclusion.

Subpart E—Notice and Appeals

- 1001.2001 Notice of intent to exclude.
- 1001.2002 Notice of exclusion.

- 1001.2003 Notice of proposal to exclude.
- 1001.2004 Notice to State agencies.
- 1001.2005 Notice to State licensing agencies.
- 1001.2006 Notice to others regarding exclusion.
- 1001.2007 Appeal of exclusions.

Subpart F—Reinstatement into the Programs

- 1001.3001 Timing and method of request for reinstatement.
- 1001.3002 Basis for reinstatement.
- 1001.3003 Approval of request for reinstatement.
- 1001.3004 Denial of request for reinstatement.
- 1001.3005 Reversed or vacated decisions.

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Subpart A—General Provisions

§ 1001.1 Scope and purpose.

(a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicare and certain State health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.

(b) The regulations in this part are applicable to and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG (and, where applicable, in imposing exclusions proposed by the OIG).

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993]

§ 1001.2 Definitions.

Controlled substance means a drug or other substance, or immediate precursor:

(a) Included in schedules I, II, III, IV or V of part B of subchapter I in 21 U.S.C. chapter 13, or

(b) That is deemed a controlled substance by the law of any State.

Convicted means that—

(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:

(1) There is a post-trial motion or an appeal pending, or

(2) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(b) A Federal, State or local court has made a finding of guilt against an individual or entity;

(c) A Federal, State or local court has accepted a plea of guilty or *nolo contendere* by an individual or entity; or

(d) An individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

Exclusion means that items and services furnished by a specified individual or entity will not be reimbursed under Medicare or the State health care programs.

HHS means Department of Health and Human Services.

OIG means Office of Inspector General of the Department of Health and Human Services.

PRO means Utilization and Quality Control Peer Review Organization as created by the Tax Equity and Fiscal Responsibility Act of 1982 (42 U.S.C. 1320c-3).

Professionally recognized standards of health care are Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. Where the Food and Drug Administration (FDA), the Health Care Financing Administration (HCFA) or the Public Health Service (PHS) has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of

health care. This definition shall not be construed to mean that all other treatments meet professionally recognized standards.

Sole community physician means a physician who is the only physician who provides primary care services to Federal or State health care program beneficiaries within a defined service area.

Sole source of essential specialized services in the community means that an individual or entity—

(a) Is the only practitioner, supplier or provider furnishing specialized services in an area designated by the Public Health Service as a health manpower shortage area for that medical specialty, as listed in 42 CFR part 5, appendices B-F;

(b) Is a sole community hospital, as defined in §412.92 of this title; or

(c) Is the only source for specialized services in a defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

State health care program means:

(a) A State plan approved under title XIX of the Act (Medicaid),

(b) Any program receiving funds under title V of the Act or from an allotment to a State under such title (Maternal and Child Health Services Block Grant program), or

(c) Any program receiving funds under title XX of the Act or from any allotment to a State under such title (Block Grants to States for Social Services).

State Medicaid Fraud Control Unit means a unit certified by the Secretary as meeting the criteria of 42 U.S.C. 1396b(q) and §1002.305 of this chapter.

Subpart B—Mandatory Exclusions

§ 1001.101 Basis for liability.

The OIG will exclude any individual or entity that—

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program, or

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients. The conviction need not relate to a patient who is a program beneficiary.

§ 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with § 1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, resulted in financial loss to Medicare and the State health care programs of \$1,500 or more. (The entire amount of financial loss to such programs will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made to the programs);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;

(4) The sentence imposed by the court included incarceration;

(5) The convicted individual or entity has a prior criminal, civil or administrative sanction record; or

(6) The individual or entity has at any time been overpaid a total of \$1,500 or more by Medicare or State health care programs as a result of improper billings.

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating—

(1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss to Medicare and the State

health care programs due to the acts that resulted in the conviction, and similar acts, is less than \$1,500;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; or

(3) The individual's or entity's cooperation with Federal or State officials resulted in—

(i) Others being convicted or excluded from Medicare or any of the State health care programs, or

(ii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

Subpart C—Permissive Exclusions

§ 1001.201 Conviction relating to program or health care fraud.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(1) In connection with the delivery of any health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(2) With respect to any act or omission in a program operated by, or financed in whole or in part by, any Federal, State or local government agency.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts resulting in the conviction, or similar acts, resulted in financial loss of \$1,500 or more to a government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals. (The total amount of

financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made.);

(ii) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(iii) The acts that resulted in the conviction, or similar acts, had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals;

(iv) The sentence imposed by the court included incarceration; or

(v) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss to a government program or to other individuals or entities due to the acts that resulted in the conviction and similar acts is less than \$1,500;

(ii) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(iii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; or

(iv) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.301 Conviction relating to obstruction of an investigation.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation into any criminal offense described in §§ 1001.101 or 1001.201.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The interference with, or obstruction of, the investigation caused the expenditure of significant additional time or resources;

(ii) The interference or obstruction had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or on the Medicare or State health care programs;

(iii) The interference or obstruction also affected a civil or administrative investigation;

(iv) The sentence imposed by the court included incarceration; or

(v) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The record of the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992]

§ 1001.401 Conviction relating to controlled substances.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law.

(b) For purposes of this section, the definition of *controlled substance* will be the definition that applies to the law forming the basis for the conviction.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the conviction or similar acts were committed over a period of one year or more;

(ii) The acts that resulted in the conviction or similar acts had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals or the Medicare or State health care programs;

(iii) The sentence imposed by the court included incarceration; or

(iv) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for shortening the period of exclusion—

(i) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.501 License revocation or suspension.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has—

(1) Had a license to provide health care revoked or suspended by any State licensing authority, or has otherwise lost such a license (including the right to apply for or renew such a license), for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity; or

(2) Has surrendered such a license while a formal disciplinary proceeding concerning the individual's or entity's professional competence, professional performance or financial integrity was pending before a State licensing authority.

(b) *Length of exclusion.* (1) Except as provided in paragraph (c) of this section, an exclusion imposed in accordance with this section will never be for a period of time less than the period during which an individual's or entity's license is revoked, suspended or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the revocation, suspension or loss of the individual's or entity's license to provide health care had or could have had a significant adverse physical, emotional or financial impact on one or more program beneficiaries or other individuals;

(ii) The individual or entity has a prior criminal, civil or administrative sanction record; or

(iii) The acts (or similar acts) had or could have had a significant adverse impact on the financial integrity of the programs.

(3) Only if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may mitigating factors be considered as a basis for reducing the period of exclusion to a period not less than that

set forth in paragraph (b)(1) of this section. Only the following factors may be considered mitigating—

(i) The individual's or entity's cooperation with a State licensing authority resulted in the sanctioning of other individuals or entities; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

(4) When an individual or entity has been excluded under this section, the OIG will consider a request for reinstatement in accordance with § 1001.3001 if the individual or entity obtains a valid license in the State where the license was originally revoked, suspended, surrendered or otherwise lost.

(c) *Exceptions*—(1) *Length of exclusion*. If, prior to the notice of exclusion by the OIG, the licensing authority of a State (other than the one in which the individual's or entity's license had been revoked, suspended, surrendered or otherwise lost), being fully apprised of all of the circumstances surrounding the prior action by the licensing board of the first State, grants the individual or entity a license or takes no significant adverse action as to a currently held license, an exclusion imposed in accordance with this section may be for a period of time less than that prescribed by paragraph (b)(1) of this section.

(2) *Consideration of early reinstatement*. If an individual or entity that has been excluded in accordance with this section fully and accurately discloses the circumstances surrounding this action to a licensing authority of a different State, and that State grants the individual or entity a new license or takes no significant adverse action as to a currently held license, the OIG will consider a request for early reinstatement.

§ 1001.601 Exclusion or suspension under a Federal or State health care program.

(a) *Circumstance for exclusion*. (1) The OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under—

(i) Any Federal program involving the provision of health care, or

(ii) A State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity.

(2) The term “or otherwise sanctioned” in paragraph (a)(1) of this section is intended to cover all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called, and includes situations where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

(b) *Length of exclusion*. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the exclusion, suspension or other sanction under the Federal or State health care program had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals;

(ii) The period of exclusion, suspension or other sanction imposed under the Federal or State health care program is greater than 3 years; or

(iii) The individual or entity has a prior criminal, civil or administrative record.

(3) Only the following factors may be considered mitigating and a basis for shortening the period of exclusion—

(i) The period of exclusion, suspension or other sanction imposed under the Federal or State health care program is less than 3 years;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in the sanctioning of other individuals or entities; or

(iii) Alternative sources of the types of health care items or services furnished by the individual or entity are not available.

(4) The OIG will normally not consider a request for reinstatement in accordance with §1001.3001 until the period of exclusion imposed by the OIG has expired.

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity that has—

(1) Submitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual's or entity's usual charges or costs for such items or services; or

(2) Furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(b) The OIG's determination under paragraph (a)(2) of this section—that the items or services furnished were excessive or of unacceptable quality—will be made on the basis of information, including sanction reports, from the following sources:

(1) The PRO for the area served by the individual or entity;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies; or

(5) Any other sources deemed appropriate by the OIG.

(c) Exceptions. An individual or entity will not be excluded for—

(1) Submitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause; or

(2) Furnishing, or causing to be furnished, items or services in excess of

the needs of patients, when the items or services were ordered by a physician or other authorized individual, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician or other authorized individual.

(d) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (d)(2) and (d)(3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The violations were serious in nature, and occurred over a period of one year or more;

(ii) The violations had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals;

(iii) The individual or entity has a prior criminal, civil or administrative sanction record; or

(iv) The violation resulted in financial loss to Medicare or the State health care programs of \$1,500 or more.

(3) Only the following factors may be considered mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.801 Failure of HMOs and CMPs to furnish medically necessary items and services.

(a) Circumstances for exclusion. The OIG may exclude an entity—

(1) That is a—

(i) Health maintenance organization (HMO), as defined in section 1903(m) of the Act, providing items or services under a State Medicaid Plan;

(ii) Primary care case management system providing services, in accordance with a waiver approved under section 1915(b)(1) of the Act; or

(iii) HMO or competitive medical plan providing items or services in accordance with a risk-sharing contract under section 1876 of the Act;

(2) That has failed substantially to provide medically necessary items and services that are required under a plan, waiver or contract described in paragraph (a)(1) of this section to be provided to individuals covered by such plan, waiver or contract; and

(3) Where such failure has adversely affected or has a substantial likelihood of adversely affecting covered individuals.

(b) The OIG's determination under paragraph (a)(2) of this section—that the medically necessary items and services required under law or contract were not provided—will be made on the basis of information, including sanction reports, from the following sources:

(1) The PRO or other quality assurance organization under contract with a State Medicaid plan for the area served by the HMO or competitive medical plan;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies;

(5) HCFA's HMO compliance office; or

(6) Any other sources deemed appropriate by the OIG.

(c) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (c)(2) and (c)(3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The entity failed to provide a large number or a variety of items or services;

(ii) The failures occurred over a lengthy period of time;

(iii) The entity's failure to provide a necessary item or service had or could have had a serious adverse effect; or

(iv) The entity has a criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) Alternative sources of the type of health care items or services furnished by the entity are not available.

(iii) The entity took corrective action upon learning of impermissible activities by an employee or contractor.

§ 1001.901 False or improper claims.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that it determines has committed an act described in section 1128A of the Act. The imposition of a civil money penalty or assessment is not a prerequisite for an exclusion under this section.

(b) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors—

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed;

(2) The degree of culpability;

(3) The individual's or entity's prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and

(4) Other matters as justice may require.

§ 1001.951 Fraud and kickbacks and other prohibited activities.

(a) *Circumstance for exclusion.* (1) Except as provided for in paragraph (a)(2)(ii) of this section, the OIG may exclude any individual or entity that it determines has committed an act described in section 1128B(b) of the Act.

(2) With respect to acts described in section 1128B of the Act, the OIG—

(i) May exclude any individual or entity that it determines has knowingly and willfully solicited, received, offered or paid any remuneration in the manner and for the purposes described therein, irrespective of whether the individual or entity may be able to prove

that the remuneration was also intended for some other purpose; and

(ii) Will not exclude any individual or entity if that individual or entity can prove that the remuneration that is the subject of the exclusion is exempted from serving as the basis for an exclusion.

(b) *Length of exclusion.* (1) The following factors will be considered in determining the length of exclusion in accordance with this section—

(i) The nature and circumstances of the acts and other similar acts;

(ii) The nature and extent of any adverse physical, mental, financial or other impact the conduct had on program beneficiaries or other individuals or the Medicare or State health programs;

(iii) The excluded individual's or entity's prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and

(iv) Any other facts bearing on the nature and seriousness of the individual's or entity's misconduct.

(2) It will be considered a mitigating factor if—

(i) The individual had a documented mental, emotional, or physical condition before or during the commission of the prohibited act(s) that reduced the individual's culpability for the acts in question;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in the—

(A) Sanctioning of other individuals or entities, or

(B) Imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services provided by the individual or entity are not available.

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

(a) *Investment Interests.* As used in section 1128B of the Act, "remuneration" does not include any payment that is a return on an investment interest, such as a dividend or interest

income, made to an investor as long as all of the applicable standards are met within one of the following two categories of entities:

(1) If, within the previous fiscal year or previous 12 month period, the entity possesses more than \$50,000,000 in undepreciated net tangible assets (based on the net acquisition cost of purchasing such assets from an unrelated entity) related to the furnishing of items and services, all of the following five applicable standards must be met—

(i) With respect to an investment interest that is an equity security, the equity security must be registered with the Securities and Exchange Commission under 15 U.S.C. 781 (b) or (g).

(ii) The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms equally available to the public through trading on a registered national securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or on the National Association of Securities Dealers Automated Quotation System.

(iii) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(iv) The entity must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.

(2) If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met—

(i) No more than 40 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous

12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.

(ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(vi) No more than 40 percent of the gross revenue of the entity in the previous fiscal year or previous 12 month period may come from referrals, items or services furnished, or business otherwise generated from investors.

(vii) The entity must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

For purposes of paragraph (a) of this section, the following terms apply. Ac-

tive investor means an investor either who is responsible for the day-to-day management of the entity and is a bona fide general partner in a partnership under the Uniform Partnership Act or who agrees in writing to undertake liability for the actions of the entity's agents acting within the scope of their agency. *Investment interest* means a security issued by an entity, and may include the following classes of investments: shares in a corporation, interests or units of a partnership, bonds, debentures, notes, or other debt instruments. *Investor* means an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest. *Passive investor* means an investor who is not an active investor, such as a limited partner in a partnership under the Uniform Partnership Act, a shareholder in a corporation, or a holder of a debt security.

(b) *Space Rental*. As used in section 1128B of the Act, "remuneration" does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following five standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease specifies the premises covered by the lease.

(3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole

or in part under Medicare or a State health care program.

For purposes of paragraph (b) of this section, the term *fair market value* means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program.

(c) *Equipment rental.* As used in section 1128B of the Act, “remuneration” does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following five standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease specifies the equipment covered by the lease.

(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

For purposes of paragraph (c) of this section, the term *fair market value* means the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in

part under Medicare or a State health care program.

(d) *Personal services and management contracts.* As used in section 1128B of the Act, “remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following six standards are met—

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

(6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

(e) *Sale of practice.* As used in section 1128B of the Act, “remuneration” does not include any payment made to a practitioner by another practitioner where the former practitioner is selling his or her practice to the latter practitioner, as long as both of the following two standards are met—

(1) The period from the date of the first agreement pertaining to the sale

to the completion of the sale is not more than one year.

(2) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare or a State health care program after one year from the date of the first agreement pertaining to the sale.

(f) *Referral services.* As used in section 1128B of the Act, “remuneration” does not include any payment or exchange of anything of value between an individual or entity (“participant”) and another entity serving as a referral service (“referral service”), as long as all of the following four standards are met—

(1) The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by the participants for the referral service for which payment may be made in whole or in part under Medicare or a State health care program.

(3) The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.

(4) The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service—

(i) The manner in which it selects the group of participants in the referral

service to which it could make a referral;

(ii) Whether the participant has paid a fee to the referral service;

(iii) The manner in which it selects a particular participant from this group for that person;

(iv) The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and

(v) The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.

(g) *Warranties.* As used in section 1128B of the Act, “remuneration” does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and (g)(2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) and (g)(4) of this section—

(1) The buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.

(2) The buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier as specified in paragraph (g)(3) of this section.

(3) The manufacturer or supplier must comply with either of the following two standards—

(i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (a)(1) and (a)(2) of this section.

(ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its

obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

For purposes of paragraph (g) of this section, the term *warranty* means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item (which is covered by an agreement made in accordance with this statutory provision), on terms equal to the agreement that it replaces.

(h) *Discounts*. As used in section 1128B of the Act, "remuneration" does not include a discount, as defined in paragraph (h)(3) of this section, on a good or service received by a buyer, which submits a claim or request for payment for the good or service for which payment may be made in whole or in part under Medicare or a State health care program, from a seller as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section and the seller complies with the applicable standards of paragraph (h)(2) of this section:

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within each category—

(i) If the buyer is an entity which reports its costs on a cost report required by the Department or a State agency, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section.

(ii) If the buyer is an entity which is a health maintenance organization or competitive medical plan acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(iii) If the buyer is not an entity described in paragraphs (h)(1)(i) or (h)(1)(ii) of this section, it must comply with all of the following three standards—

(A) The discount must be made at the time of the original sale of the good or service;

(B) Where an item or service is separately claimed for payment with the Department or a State agency, the buyer must fully and accurately report the discount on that item or service; and

(C) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii)(A) of this section.

(2) With respect to either of the following two categories of buyers, the seller must comply with all of the applicable standards within each category—

(i) If the buyer is an entity described in paragraph (h)(1)(ii) of this section, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is any other individual or entity, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to the Department or a State agency under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice or statement submitted to the buyer, and inform the buyer of its obligations to report such discount; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the

invoice or statement submitted to the buyer, inform the buyer of its obligations under paragraph (h)(1) of this section and, when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied.

(3) For purposes of this paragraph, the term *discount* means a reduction in the amount a seller charges a buyer (who buys either directly or through a wholesaler or a group purchasing organization) for a good or service based on an arms length transaction. The term *discount* may include a rebate check, credit or coupon directly redeemable from the seller only to the extent that such reductions in price are attributable to the original good or service that was purchased or furnished. The term *discount* does not include—

- (i) Cash payment;
- (ii) Furnishing one good or service without charge or at a reduced charge in exchange for any agreement to buy a different good or service;
- (iii) A reduction in price applicable to one payor but not to Medicare or a State health care program;
- (iv) A reduction in price offered to a beneficiary (such as a routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary);
- (v) Warranties;
- (vi) Services provided in accordance with a personal or management services contract; or
- (vii) Other remuneration in cash or in kind not explicitly described in this paragraph.

(i) *Employees*. As used in section 1128B of the Act, “remuneration” does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State health care program. For purposes of paragraph (i) of this section, the term *employee* has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

(j) *Group purchasing organizations*. As used in section 1128B of the Act, “remuneration” does not include any pay-

ment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met—

(1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following—

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

For purposes of paragraph (j) of this section, the term *group purchasing organization* (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare or a State health care program, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

(k) *Waiver of beneficiary coinsurance and deductible amounts*. As used in section 1128B of the Act, “remuneration” does not include any reduction or waiver of a Medicare or a State health care program beneficiary’s obligation to

pay coinsurance or deductible amounts as long as all of the standards are met within either of the following two categories of health care providers:

(1) If the coinsurance or deductible amounts are owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system, the hospital must comply with all of the following three standards—

(i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals.

(ii) The hospital must offer to reduce or waive the coinsurance or deductible amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for Medicare reimbursement is filed.

(iii) The hospital's offer to reduce or waive the coinsurance or deductible amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (1)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

(2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under title V of the Act, the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

(1) *Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans.* (1) As used in section 1128B of the Act, “remuneration” does not include the additional coverage of any item or service offered by a health plan to an enrollee

or the reduction of some or all of the enrollee's obligation to pay the health plan or a contract health care provider for cost-sharing amounts (such as coinsurance, deductible, or copayment amounts) or for premium amounts attributable to items or services covered by the health plan, the Medicare program, or a State health care program, as long as the health plan complies with all of the standards within one of the following two categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, prepaid health plan, or other health plan under contract with HCFA or a State health care program and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, it must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract unless otherwise approved by HCFA or by a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan or other health plan that has executed a contract or agreement with HCFA or with a State health care program to receive payment for enrollees on a reasonable cost or similar basis, it must comply with both of the following two standards—

(A) The health plan must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract or agreement unless otherwise approved by HCFA or by a State health care program; and

(B) The health plan must not claim the costs of the increased coverage or the reduced cost-sharing or premium amounts as a bad debt for payment purposes under Medicare or a State health care program or otherwise shift the burden of the increased coverage or reduced cost-sharing or premium amounts to the extent that increased

payments are claimed from Medicare or a State health care program.

(2) For purposes of paragraph (1) of this section, the terms—

Contract health care provider means an individual or entity under contract with a health plan to furnish items or services to enrollees who are covered by the health plan, Medicare, or a State health care program.

Enrollee means an individual who has entered into a contractual relationship with a health plan (or on whose behalf an employer, or other private or governmental entity has entered into such a relationship) under which the individual is entitled to receive specified health care items and services, or insurance coverage for such items and services, in return for payment of a premium or a fee.

Health plan means an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, where such entity:

(i) Operates in accordance with a contract, agreement or statutory demonstration authority approved by HCFA or a State health care program;

(ii) Charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations;

(iii) Is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or

(iv) Is licensed in the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) of this definition, and is paid a fee for the administration of the plan which reflects the fair market value of those services.

(m) *Price reductions offered to health plans.* (1) As used in section 1128B of the Act, “remuneration” does not include a reduction in price a contract health care provider offers to a health plan in accordance with the terms of a written agreement between the con-

tract health care provider and the health plan for the sole purpose of furnishing to enrollees items or services that are covered by the health plan, Medicare, or a State health care program, as long as both the health plan and contract health care provider comply with all of the applicable standards within one of the following four categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, or prepaid health plan under contract with HCFA or a State agency and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, the contract health care provider must not claim payment in any form from the Department or the State agency for items or services furnished in accordance with the agreement except as approved by HCFA or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan, or other health plan that has executed a contract or agreement with HCFA or a State health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and contract health care provider must comply with all of the following four standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, and the methodology for computing the payment to the contract health care provider;

(C) The health plan must fully and accurately report, on the applicable cost report or other claim form filed with the Department or the State health care program, the amount it has paid the contract health care provider

under the agreement for the covered items and services furnished to enrollees; and

(D) The contract health care provider must not claim payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement except as approved by HCFA or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iii) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section and the contract health care provider is not paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following six standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, which party is to file claims or requests for payment with Medicare or the State health care program for such items and services, and the schedule of fees the contract health care provider will charge for furnishing such items and services to enrollees;

(C) The fee schedule contained in the agreement between the health plan and the contract health care provider must remain in effect throughout the term of the agreement, unless a fee increase results directly from a payment update authorized by Medicare or the State health care program;

(D) The party submitting claims or requests for payment from Medicare or the State health care program for items and services furnished in accordance with the agreement must not claim or request payment for amounts in excess of the fee schedule;

(E) The contract health care provider and the health plan must fully and accurately report on any cost report filed with Medicare or a State health care program the fee schedule amounts charged in accordance with the agree-

ment and, upon request, will report to the Medicare or a State health care program the terms of the agreement and the amounts paid in accordance with the agreement; and

(F) The party to the agreement, which does not have the responsibility under the agreement for filing claims or requests for payment, must not claim or request payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iv) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section, and the contract health care provider is paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following five standards—

(A) The term of the agreement between the health plan and the contract health provider must be for not less than one year;

(B) The agreement between the health plan and the contract health provider must specify in advance the covered items and services to be furnished to enrollees and the total amount per enrollee (which may be expressed in a per month or other time period basis) the contract health care provider will be paid by the health plan for furnishing such items and services to enrollees and must set forth any co-payments, if any, to be paid by enrollees to the contract health care provider for covered services;

(C) The payment amount contained in the agreement between the health care plan and the contract health care provider must remain in effect throughout the term of the agreement;

(D) The contract health care provider and the health plan must fully and accurately report to the Medicare and State health care program upon request, the terms of the agreement and the amounts paid in accordance with the agreement; and

(E) The contract health care provider must not claim or request payment in any form from the Department, a State

health care program or an enrollee (other than copayment amounts described in paragraph (m)(2)(iv)(B) of this section) and the health plan must not pay the contract care provider in excess of the amounts described in paragraph (m)(2)(iv)(B) of this section for items and services covered by the agreement.

(2) For purposes of this paragraph, the terms *contract health care provider*, *enrollee*, and *health plan* have the same meaning as in paragraph (l)(2) of this section.

[57 FR 3330, Jan. 29, 1992, as amended at 57 FR 52729, Nov. 5, 1992; 61 FR 2135, Jan. 25, 1996]

§ 1001.953 OIG report on compliance with investment interest safe harbor.

Within 180 days of the effective date of this subpart, the OIG will report to the Secretary on the compliance with §§ 1001.952(a)(2)(i) and 1001.952(a)(2)(vi).

§ 1001.1001 Exclusion of entities owned or controlled by a sanctioned person.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an entity if:

(i) A person with a relationship with such entity—

(A) Has been convicted of a criminal offense as described in sections 1128(a) and 1128(b) (1), (2) or (3) of the Act;

(B) Has had civil money penalties or assessments imposed under section 1128A of the Act; or

(C) Has been excluded from participation in Medicare or any of the State health care programs, and

(ii) Such a person—

(A) Has a direct or indirect ownership interest (or any combination thereof) of 5 percent or more in the entity;

(B) Is the owner of a whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof, in which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(C) Is an officer or director of the entity, if the entity is organized as a corporation;

(D) Is a partner in the entity, if the entity is organized as a partnership;

(E) Is an agent of the entity; or

(F) Is a managing employee, that is, an individual (including a general manager, business manager, administrator or director) who exercises operational or managerial control over the entity or part thereof, or directly or indirectly conducts the day-to-day operations of the entity or part thereof.

(2) For purposes of this section, the term:

Agent means any person who has express or implied authority to obligate or act on behalf of an entity.

Indirect ownership interest includes an ownership interest through any other entities that ultimately have an ownership interest in the entity in issue. (For example, an individual has a 10 percent ownership interest in the entity at issue if he or she has a 20 percent ownership interest in a corporation that wholly owns a subsidiary that is a 50 percent owner of the entity in issue.)

Ownership interest means an interest in:

(i) The capital, the stock or the profits of the entity, or

(ii) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.

(b) *Length of exclusion.* (1) Except as provided in § 1001.3002(c), exclusions under this section will be for the same period as that of the individual whose relationship with the entity is the basis for this exclusion, if the individual has been or is being excluded.

(2) If the individual was not excluded, the length of the entity's exclusion will be determined by considering the factors that would have been considered if the individual had been excluded.

(3) An entity excluded under this section may apply for reinstatement at any time in accordance with the procedures set forth in § 1001.3001(a)(2).

§ 1001.1101 Failure to disclose certain information.

(a) *Circumstance for exclusion.* The OIG may exclude any entity that did not fully and accurately, or completely, make disclosures as required by section 1124, 1124A or 1126 of the Act, and by part 455, subpart B and part 420, subpart C of this title.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

- (1) The number of instances where full and accurate, or complete, disclosure was not made;
- (2) The significance of the undisclosed information;
- (3) The entity's prior criminal, civil and administrative sanction record (The lack of any prior record is to be considered neutral);
- (4) Any other facts that bear on the nature or seriousness of the conduct;
- (5) The availability of alternative sources of the type of health care services provided by the entity; and
- (6) The extent to which the entity knew that the disclosures made were not full or accurate.

§ 1001.1201 Failure to provide payment information.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that furnishes items or services for which payment may be made under Medicare or any of the State health care programs and that:

- (1) Fails to provide such information as is necessary to determine whether such payments are or were due and the amounts thereof, or
- (2) Has refused to permit such examination and duplication of its records as may be necessary to verify such information.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

- (1) The number of instances where information was not provided;
- (2) The circumstances under which such information was not provided;
- (3) The amount of the payments at issue;
- (4) The individual's or entity's criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and
- (5) The availability of alternative sources of the type of health care items or services provided by the individual or entity.

§ 1001.1301 Failure to grant immediate access.

(a) *Circumstance for exclusion.* (1) The OIG may exclude any individual or entity that fails to grant immediate access upon reasonable request to—

- (i) The Secretary, a State survey agency or other authorized entity for the purpose of determining, in accordance with section 1864(a) of the Act, whether—

(A) An institution is a hospital or skilled nursing facility;

(B) An agency is a home health agency;

(C) An agency is a hospice program;

(D) A facility is a rural health clinic as defined in section 1861(aa)(2) of the Act, or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2) of the Act;

(E) A laboratory is meeting the requirements of section 1861(s) (15) and (16) of the Act, and section 353(f) of the Public Health Service Act;

(F) A clinic, rehabilitation agency or public health agency is meeting the requirements of section 1861(p)(4) (A) or (B) of the Act;

(G) An ambulatory surgical center is meeting the standards specified under section 1832(a)(2)(F)(i) of the Act;

(H) A portable x-ray unit is meeting the requirements of section 1861(s)(3) of the Act;

(I) A screening mammography service is meeting the requirements of section 1834(c)(3) of the Act;

(J) An end-stage renal disease facility is meeting the requirements of section 1881(b) of the Act;

(K) A physical therapist in independent practice is meeting the requirements of section 1861(p) of the Act;

(L) An occupational therapist in independent practice is meeting the requirements of section 1861(g) of the Act;

(M) An organ procurement organization meets the requirements of section 1138(b) of the Act; or

(N) A rural primary care hospital meets the requirements of section 1820(i)(2) of the Act;

- (ii) The Secretary, a State survey agency or other authorized entity to perform the reviews and surveys required under State plans in accordance

with sections 1902(a)(26) (relating to inpatient mental hospital services), 1902(a)(31) (relating to intermediate care facilities for the mentally retarded), 1919(g) (relating to nursing facilities), 1929(i) (relating to providers of home and community care and community care settings), 1902(a)(33) and 1903(g) of the Act;

(iii) The OIG for the purposes of reviewing records, documents and other data necessary to the performance of the Inspector General's statutory functions; or

(iv) A State Medicaid fraud control unit for the purpose of conducting its activities.

(2) For purposes of paragraphs (a)(1)(i) and (a)(1)(ii) of this section, the term—

Failure to grant immediate access means the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.

Reasonable request means a written request made by a properly identified agent of the Secretary, of a State survey agency or of another authorized entity, during hours that the facility, agency or institution is open for business.

The request will include a statement of the authority for the request, the rights of the entity in responding to the request, the definition of *reasonable request* and *immediate access*, and the penalties for failure to comply, including when the exclusion will take effect.

(3) For purposes of paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the term—

Failure to grant immediate access means:

(i) Except where the OIG or State Medicaid fraud control unit reasonably believes that requested documents are about to be altered or destroyed, the failure to produce or make available for inspection and copying requested records upon reasonable request, or to provide a compelling reason why they cannot be produced, within 24 hours of such request;

(ii) Where the OIG or State Medicaid fraud control unit has reason to believe that requested documents are about to be altered or destroyed, the failure to

provide access to requested records at the time the request is made.

Reasonable request means a written request for documents, signed by a designated representative of the OIG or the State Medicaid fraud control unit, and made by a properly identified agent of the OIG or a State Medicaid fraud control unit during reasonable business hours, where there is information to suggest that the individual or entity has violated statutory or regulatory requirements under titles V, XI, XVIII, XIX or XX of the Act. The request will include a statement of the authority for the request, the rights of the individual or entity in responding to the request, the definition of *reasonable request* and *immediate access*, and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

(4) Nothing in this section shall in any way limit access otherwise authorized under State or Federal law.

(b) *Length of exclusion.* (1) An exclusion of an individual under this section may be for a period equal to the sum of:

(i) The length of the period during which the immediate access was not granted, and

(ii) An additional period of up to 90 days.

(2) The exclusion of an entity may be for a longer period than the period in which immediate access was not granted based on consideration of the following factors—

(i) The impact of the failure to grant the requested immediate access on Medicare or any of the State health care programs, beneficiaries or the public;

(ii) The circumstances under which such access was refused;

(iii) The impact of the exclusion on Medicare or any of the State health care programs, beneficiaries or the public; and

(iv) The entity's prior criminal, civil or administrative sanction record (the lack of any prior record is to be considered neutral).

(3) For purposes of paragraphs (b)(1) and (b)(2) of this section, the length of

the period in which immediate access was not granted will be measured from the time the request is made, or from the time by which access was required to be granted, whichever is later.

(c) The exclusion will be effective as of the date immediate access was not granted.

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 40753, July 30, 1993]

§ 1001.1401 Violations of PPS corrective action.

(a) *Circumstance for exclusion.* The OIG may exclude any hospital that HCFA determines has failed substantially to comply with a corrective action plan required by HCFA under section 1886(f)(2)(B) of the Act.

(b) *Length of exclusion.* The following factors will be considered in determining the length of exclusion under this section—

(1) The impact of the hospital's failure to comply on Medicare or any of the State health care programs, program beneficiaries or other individuals;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the exclusion on Medicare or any of the State health care programs, beneficiaries or the public; and

(5) The hospital's prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral).

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) *Circumstance for exclusion.* (1) Except as provided in paragraph (a)(4) of this section, the OIG may exclude any individual that the Public Health Service (PHS) determines is in default on repayments of scholarship obligations or loans in connection with health professions education made or secured in whole or in part by the Secretary.

(2) Before imposing an exclusion in accordance with paragraph (a)(1) of this section, the OIG must determine that PHS has taken all reasonable administrative steps to secure repayment of the loans or obligations. If PHS has offered a Medicare offset arrangement as required by section 1892 of the Act,

the OIG will find that all reasonable steps have been taken.

(3) The OIG will take into account access of beneficiaries to physicians' services for which payment may be made under Medicare or State health care programs in determining whether to impose an exclusion.

(4) The OIG will not exclude a physician who is the sole community physician or the sole source of essential specialized services in a community if a State requests that the physician not be excluded.

(b) *Length of exclusion.* The individual will be excluded until such time as PHS notifies the OIG that the default has been cured or the obligations have been resolved to the PHS's satisfaction. Upon such notice, the OIG will inform the individual of his or her right to request reinstatement.

§ 1001.1601 Violations of the limitations on physician charges.

(a) *Circumstance for exclusion.* (1) The OIG may exclude a physician whom it determines—

(i) Is a non-participating physician under section 1842(j) of the Act;

(ii) Furnished services to a beneficiary;

(iii) Knowingly and willfully billed—

(A) On a repeated basis for such services actual charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990, or

(B) Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984 to December 31, 1986; and"

(iv) Is not the sole community physician or sole source of essential specialized services in the community.

(2) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(b) *Length of exclusion.* (1) In determining the length of an exclusion in

accordance with this section, the OIG will consider the following factors—

- (i) The number of services for which the physician billed in excess of the maximum allowable charges;
 - (ii) The number of beneficiaries for whom services were billed in excess of the maximum allowable charges;
 - (iii) The amount of the charges that were in excess of the maximum allowable charges;
 - (iv) The physician's prior criminal, civil or administrative sanction record (the lack of any prior record is to be considered neutral); and
 - (v) The availability of alternative sources of the type of health care items or services furnished by the physician.
- (2) The period of exclusion may not exceed 5 years.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992]

§ 1001.1701 Billing for services of assistant at surgery during cataract operations.

(a) Circumstance for exclusion. The OIG may exclude a physician whom it determines—

- (1) Has knowingly and willfully presented or caused to be presented a claim, or billed an individual enrolled under Part B of the Medicare program (or his or her representative) for:

- (i) Services of an assistant at surgery during a cataract operation, or
 - (ii) Charges that include a charge for an assistant at surgery during a cataract operation;

- (2) Has not obtained prior approval for the use of such assistant from the appropriate Utilization and Quality Control Peer Review Organization (PRO) or Medicare carrier; and

- (3) Is not the sole community physician or sole source of essential specialized services in the community.

(b) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

- (i) The number of instances for which claims were submitted or beneficiaries

were billed for unapproved use of assistants during cataract operations;

- (ii) The amount of the claims or bills presented;

- (iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;

- (iv) Whether approval for the use of an assistant was requested from the PRO or carrier;

- (v) The physician's criminal, civil or administrative sanction record (the lack of any prior record is to be considered neutral); and

- (vi) The availability of alternative sources of the type of health care items or services furnished by the physician.

- (2) The period of exclusion may not exceed 5 years.

Subpart D—Waivers and Effect of Exclusion

§ 1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from a State health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The request must be in writing and from an individual directly responsible for administering the State health care program.

(b) With respect to exclusions under § 1001.101(a), a request from a State health care program for a waiver of the exclusion will only be considered if the individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(c) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if the OIG determines that imposition of the exclusion would not be in the public interest.

(d) If the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

(f) The decision to grant, deny or rescind a request for a waiver is not subject to administrative or judicial review.

(g) The Inspector General may waive the exclusion of an individual or entity from participation in the Medicare program in conjunction with granting a waiver requested by a State health care program. If a State program waiver is rescinded, the derivative waiver of the exclusion from Medicare is automatically rescinded.

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, State health care programs, and all other Executive Branch procurement and nonprocurement programs and activities. The OIG will exclude the individual or entity from the Medicare program and direct State agency administering a State health care program to exclude the individual or entity for the same period. In the case of an individual or entity not eligible to participate in Medicare, the exclusion will still be effective on the date, and for the period, established by the OIG.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare program in accordance with subpart F of this part, no payment will be made by Medicare or any of the State health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion.

(2) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(3) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is

subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act.

(c) *Exceptions to paragraph (b)(1) of this section.* (1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, HCFA will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion.

(2) HCFA will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare or a State health care program warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(i) Inpatient institutional services furnished to an individual who was admitted to an excluded institution before the date of the exclusion, and

(ii) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of exclusion.

(4) (i) Notwithstanding the other provisions of this section, payment may be made under Medicare or a State health care program for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

(ii) Notwithstanding paragraph (c)(4)(i) of this section, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.

[57 FR 3330, Jan. 29, 1992, as amended at 60 FR 32917, June 26, 1995]

Subpart E—Notice and Appeals

§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with subpart C of this part or in accordance with subpart B of this part where the exclusion is for a period exceeding 5 years, it will send written notice of its intent, the basis for the proposed exclusion, and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues.

(b) If the OIG proposes to exclude an individual or entity in accordance with §§ 1001.701 or 1001.801, the individual or entity may submit, in addition to the information described in paragraph (a) of this section, a written request to present evidence or argument orally to an OIG official.

(c) Exception. If the OIG proposes to exclude an individual or entity under the provisions of §§ 1001.1301, 1001.1401 or 1001.1501, paragraph (a) of this section will not apply.

(d) If an entity has a provider agreement under section 1866 of the Act, and the OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraphs (a) and (b) of this section will so state.

§ 1001.2002 Notice of exclusion.

(a) Except as provided in § 1001.2003, if the OIG determines that exclusion is warranted, it will send a written notice

of this decision to the affected individual or entity.

(b) The exclusion will be effective 20 days from the date of the notice.

(c) The written notice will state—

(1) The basis for the exclusion;

(2) The length of the exclusion and, where applicable, the factors considered in setting the length;

(3) The effect of the exclusion;

(4) The earliest date on which the OIG will consider a request for reinstatement;

(5) The requirements and procedures for reinstatement; and

(6) The appeal rights available to the excluded individual or entity.

(d) Paragraph (b) of this section does not apply to exclusions imposed in accordance with § 1001.1301.

§ 1001.2003 Notice of proposal to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with §§ 1001.901, 1001.951, 1001.1601 or 1001.1701, it will send written notice of this decision to the affected individual or entity. The written notice will provide the same information set forth in § 1001.2002(c). If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. The exclusion will be effective 60 days after the date of the notice unless, within that period, the individual or entity files a written request for a hearing in accordance with part 1005 of this chapter. Such request must set forth—

(1) The specific issues or statements in the notice with which the individual or entity disagrees;

(2) The basis for that disagreement;

(3) The defenses on which reliance is intended;

(4) Any reasons why the proposed length of exclusion should be modified; and

(5) Reasons why the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant the exclusion going into effect prior to the completion of an administrative law

judge (ALJ) proceeding in accordance with part 1005 of this chapter.

(b)(1) If the individual or entity does not make a written request for a hearing as provided for in paragraph (a) of this section, the OIG will send a notice of exclusion as described in § 1001.2002.

(2) If the individual or entity makes a timely written request for a hearing and the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant an immediate exclusion, an exclusion will not go into effect unless an ALJ upholds the decision to exclude.

(c) If, prior to issuing a notice of proposal to exclude under paragraph (a) of this section, the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs warrants the exclusion taking place prior to the completion of an ALJ proceeding in accordance with part 1005 of this chapter, the OIG will proceed under §§ 1001.2001 and 1001.2002.

§ 1001.2004 Notice to State agencies.

HHS will promptly notify each appropriate State agency administering or supervising the administration of each State health care program of:

(a) The facts and circumstances of each exclusion, and

(b) The period for which the State agency is being directed to exclude the individual or entity.

§ 1001.2005 Notice to State licensing agencies.

(a) HHS will promptly notify the appropriate State(s) or local agencies or authorities having responsibility for the licensing or certification of an individual or entity excluded (or directed to be excluded) from participation of the facts and circumstances of the exclusion.

(b) HHS will request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and will request that the State or local agency or authority keep the Secretary and the OIG fully and currently informed with respect to any actions taken in response to the request.

§ 1001.2006 Notice to others regarding exclusion.

(a) HHS will give notice of the exclusion and the effective date to the public, to beneficiaries (in accordance with § 1001.1901(c)), and, as appropriate, to—

(1) Any entity in which the excluded individual or entity is known to be serving as an employee, administrator, operator, or in which the individual or entity is serving in any other capacity and is receiving payment for providing services (The lack of this notice will not affect HCFA's ability to deny payment for services);

(2) State Medicaid Fraud Control Units;

(3) Utilization and Quality Control Peer Review Organizations;

(4) Hospitals, skilled nursing facilities, home health agencies and health maintenance organizations;

(5) Medical societies and other professional organizations;

(6) Contractors, health care prepayment plans, private insurance companies and other affected agencies and organizations;

(7) The State and Area Agencies on Aging established under title III of the Older Americans Act; and

(8) Other Departmental operating divisions, Federal agencies, and other agencies or organizations, as appropriate.

(b) In the case of an exclusion under § 1001.101 of this chapter, if section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) applies, HHS will give notice to the Attorney General of the United States of the facts and circumstances of the exclusion and the length of the exclusion.

§ 1001.2007 Appeal of exclusions.

(a)(1) Except as provided in § 1001.2003, an individual or entity excluded under this Part may file a request for a hearing before an ALJ only on the issues of whether:

(i) The basis for the imposition of the sanction exists, and

(ii) The length of exclusion is unreasonable.

(2) When the OIG imposes an exclusion under subpart B of this part for a period of 5 years, paragraph (a)(1)(ii) of this section will not apply.

(3) The request for a hearing should contain the information set forth in § 1005.2(d) of this chapter.

(b) The excluded individual or entity has 60 days from the receipt of notice of exclusion provided for in § 1001.2002 to file a request for such a hearing.

(c) The standard of proof at a hearing is preponderance of the evidence.

(d) When the exclusion is based on the existence of a conviction, a determination by another government agency or any other prior determination, the basis for the underlying determination is not reviewable and the individual or entity may not collaterally attack the underlying determination, either on substantive or procedural grounds, in this appeal.

(e) The procedures in part 1005 of this chapter will apply to the appeal.

Subpart F—Reinstatement into the Programs

§ 1001.3001 Timing and method of request for reinstatement.

(a)(1) Except as provided in paragraph (a)(2) of this section or in §§ 1001.501(b)(4) and (c) and 1001.601(b)(4), an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001 and 1001.1501) may submit a written request for reinstatement to the OIG only after the date specified in the notice of exclusion.

(2) An entity under § 1001.1001 may apply for reinstatement prior to the date specified in the notice of exclusion by submitting a written request for reinstatement that includes documentation demonstrating that the standards set forth in § 1001.3002(c) have been met.

(3) Upon receipt of a written request, the OIG will require the requestor to furnish specific information and authorization to obtain information from private health insurers, peer review bodies, probation officers, professional associates, investigative agencies and such others as may be necessary to determine whether reinstatement should be granted.

(4) Failure to furnish the required information or authorization will result in the continuation of the exclusion.

(b) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the individual

or entity may request reinstatement once the reduced exclusion period expires.

§ 1001.3002 Basis for reinstatement.

(a) The OIG will authorize reinstatement if it determines that—

(1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and

(3) There is no additional basis under sections 1128 (a) or (b) or 1128A of the Act for continuation of the exclusion.

(b) In making the reinstatement determination, the OIG will consider—

(1) Conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the OIG at the time of the exclusion;

(2) Conduct of the individual or entity after the date of the notice of exclusion;

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid or satisfactory arrangements have been made to fulfill these obligations;

(4) Whether HCFA has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations; and

(5) For purposes of individuals or entities excluded under part 1004 of this chapter only, the individual's or entity's willingness and ability to provide health care that meets professionally recognized standards.

(c) If the OIG determines that the criteria in paragraphs (a)(2) and (a)(3) of this section have been met, an entity excluded in accordance with § 1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion or civil money penalty was the basis for the entity's exclusion—

(1) Has reduced his or her ownership or control interest in the entity below 5 percent;

§ 1001.3003

(2) Is no longer an officer, director, agent or managing employee of the entity; or

(3) Has been reinstated in accordance with paragraph (a) of this section or § 1001.3005.

(d) Reinstatement will not be effective until OIG grants the request and provides notice under § 1001.3003(a)(1). Reinstatement will be effective as provided in the notice.

(e) A determination with respect to reinstatement is not appealable or reviewable except as provided in § 1001.3004.

(f) An ALJ may not require reinstatement of an individual or entity in accordance with this chapter.

§ 1001.3003 Approval of request for reinstatement.

(a) If the OIG grants a request for reinstatement, the OIG will—

(1) Notify HCFA of the date of the individual's or entity's reinstatement in the Medicare program;

(2) Give written notice to the excluded individual or entity specifying the date when Medicare participation may resume;

(3) Notify State agencies that administer the State health care programs that the individual or entity has been reinstated into the Medicare program; and

(4) To the extent applicable, give notice to those agencies, groups, individuals and others that were originally notified of the exclusion.

(b) If the OIG makes a determination to reinstate an individual or entity under Medicare, the State health care program upon notification from the OIG must automatically reinstate the individual or entity under such program, effective on the date of reinstatement under Medicare, unless—

(1) Reinstatement is not available to such excluded party under State law, or

(2) A longer exclusion period was established in accordance with the State's own authorities and procedures.

§ 1001.3004 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, OIG will give written notice to

42 CFR Ch. V (10–1–97 Edition)

the requesting individual or entity. Within 30 days of the date on the notice, the excluded individual or entity may submit:

(1) Documentary evidence and written argument against the continued exclusion,

(2) A written request to present written evidence and oral argument to an OIG official, or

(3) Both documentary evidence and a written request.

(b) After evaluating any additional evidence submitted by the excluded individual or entity (or at the end of the 30-day period, if none is submitted), the OIG will send written notice either confirming the denial, and indicating that a subsequent request for reinstatement will not be considered until at least one year after the date of denial, or approving the request consistent with the procedures set forth in § 1001.3003(a).

(c) The decision to deny reinstatement will not be subject to administrative or judicial review.

§ 1001.3005 Reversed or vacated decisions.

(a) An individual or entity will be reinstated into the Medicare program retroactive to the effective date of the exclusion when such exclusion is based on—

(1) A conviction that is reversed or vacated on appeal; or

(2) An action by another agency, such as a State agency or licensing board, that is reversed or vacated on appeal.

(b) If an individual or entity is reinstated in accordance with paragraph (a) of this section, HCFA will make payment for services covered under Medicare that were furnished or performed during the period of exclusion.

(c) The OIG will give notice of a reinstatement under this section in accordance with § 1001.3003(a).

(d) An action taken by OIG under this section will not require any State health care program to reinstate the individual or entity if it has imposed an exclusion under its own authority.